

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES
INTERNATIONAL, INC. and ARIUS
TWO, INC.

Plaintiffs,

C.A. No. 18-1395 (CFC) (CJB)

v.

ALVOGEN PB RESEARCH &
DEVELOPMENT LLC, ALVOGEN
MALTA OPERATIONS LTD.,
ALVOGEN PINE BROOK LLC,
ALVOGEN, INC., and ALVOGEN
GROUP, INC.,

Defendants.

PROPOSED ORDER

WHEREAS; counsel for Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook, LLC, Alvogen Inc., and Alvogen Group, Inc. (“Alvogen” or “Defendants”) submitted a Letter to the Court on August 22, 2025, seeking leave to withdraw the Declaration of Kurt Karst, D.I. 354-3. Having considered the matters raised in the Letter and the declaration of Jeremy Lowe and exhibits submitted, IT IS HEREBY ORDERED that:

Defendant Alvogen’s request to withdraw the Declaration of Kurt Karst is GRANTED. The Court will give no weight to Mr. Karst’s expert opinion in D.I. 354-

3. The Court will consider the portions of the Defendants' opposition brief, which cites to Mr. Karst's declaration in support, only as attorney argument. These portions include:

- Karst's opinion that the design-around at issue in the motion would "help increase access to high-quality lower cost generic drugs." DI 354, pg. 7.
- Karst's opinion that post-approval formulation changes submitted as ANDA supplements are "consistent with FDA practice and the agency's guidance." *Id.*
- Karst's opinion regarding whether the supplement was a "moderate" or a "minor" supplement. *Id.*
- Karst's opinion that there is "no mandated mechanism or vehicle [within FDA] for design-around." *Id.* at 9
- Karst's opinion that Alvogen's conduct before the FDA was "reasonable." *Id.*
- Karst's opinion that the administrative treatment of ANDA filings by the FDA is "irrelevant to the merits of patent infringement." *Id.* at 15.
- Karst's opinion that FDA's designations are "patent agnostic" *Id.* at 17.

The Court will treat these assertions as counsel's own legal argument regarding the characterization of the FDA filings at issue and consider the merits of all such arguments without reference to Mr. Karst's opinion.

UNITED STATES DISTRICT JUDGE